DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 10 1998

Re: LIPOSORBER® LA-15 System
Docket No. 96E-0189

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,637,994, filed by Kanegafuchi Kagaku Kogyo Kabushiki Kaisha, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for LIPOSORBER® LA-15 System, the medical device claimed by the patent.

The total length of the review period for LIPOSORBER® LA-15 System is 3,598 days. Of this time, 1,995 days occurred during the testing phase and 1,603 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun: April 18, 1986.

   FDA has verified the applicant's claim that the date the Investigational Device Exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on April 18, 1986, the date that the IDE for a similar, related product, LIPOSORBER® LA-40 System, was approved.

   Although the device was subsequently modified, the results of the initial clinical investigations on the earlier model, LIPOSORBER® LA-40 System, were included in FDA's analysis of the approved product's safety and effectiveness. The test on the earlier model is, therefore, part of the testing phase.

   Additionally, the product is of a type which, under present regulations, would require IDE approval prior to the start of clinical investigations, and normally the initiation of the testing phase for a medical device is determined by reference to the approval phase of the relevant IDE.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: October 3, 1991.

The applicant claims March 24, 1988 as the date the Premarket Approval Application (PMA) for the LIPOSORBER® LA-40 System (PMA 880019) was initially submitted, which applicant argues should be used in place of the PMA for LIPOSORBER® LA-15 System (PMA 910018). FDA records indicate that PMA 880019 was received by the agency on March 25, 1988, but this PMA was never filed, and it was withdrawn by the applicant on April 3, 1996. The applicant claims that PMA 910018 was submitted on March 26, 1991, but FDA records indicate that it was submitted on October 3, 1991.

The applicant argues that the PMA for the LA-40 device should be used as the start of the approval phase for the LA-15 device, because its liposorber technology and adsorbent are identical to those described in the patent for which applicant is requesting extension,U.S. Patent No. 4,637,994, is identical. The LA-15 device contains additional components of a plasma separator, the tubing system for plasmaphereses and the apheresis unit.

However, the patent term restoration regulations define the approval phase of medical device in terms of the actual approved product, not an earlier tested product. For example, while the patent term restoration statute does define drug product as the active ingredient of a new drug, "product" for "medical devices" has been defined as "[a]ny medical device ... subject to regulation under the Federal Food, Drug, and Cosmetic Act." 35 U.S.C. § 156(f). Given that the LA-40 device was withdrawn by applicant from further regulatory consideration, the LA-15 device is the only applicable medical device subject to FDA regulation.

Regarding the definition of regulatory review period for the start of the approval phase of a medical device, the regulations state "...the period beginning on the date the application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act ..." 35 U.S.C. § 156(g)(3)(B)(ii); see also 21 C.F.R. § 60.22(c)(2)(i). In this case, the only PMA which was submitted, filed, and approved under section 515 of the Federal Food, Drug, and Cosmetic Act was PMA P910018, which was submitted on October 3, 1991, and is, therefore, the appropriate date the approval application was initially submitted for LIPOSORBER® LA-15 System.

3. The date the application was approved: February 21, 1996.

FDA has verified the applicant's claim that PMA P910018 was approved on February 21, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis (for)

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Louis Gubinsky
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